K090084

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. (Merit) 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4748 (801) 253-6960 Susan Scott January 8, 2009 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	*ELAtion*™ Endovenous Laser Procedure Kit Vein Ablation Procedure Kit 78 GEX – Laser Instrument, Surgical, Powered
Predicate Devices	Trade Name: Common/Usual Name: Classification Name: Premarket Notification:	AngioDynamics, Inc. *NeverTouch*™ 600 µm Fiber and *VenaCure*® Procedure Kit Greater Saphenous Vein Procedure kit 78 GEX – Laser Instrument, Surgical Powered K070378, concurrence date Mar 09, 2007
	Trade Name: Common/Usual Name: Classification Name: Premarket Notification:	Vari-Lase® Endovenous Laser Procedure Kit Laser Instrument Fiber and Procedure Kit 78 GEX – Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology K051287, concurrence date Jul. 29, 2005
Classification	Class II 21 CFR §878.4810 General & Plastic Surgery	
Performance Standards	No performance standards have been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.	
Intended Use	The device is intended for use with an appropriate laser for vein ablation procedures.	
Indications for Use	The *ELAtion*™ Endovenous Laser Procedure Kit is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein and for treatment of incompetence and reflux of superficial veins in the lower extremity. The kit is intended to be used with an 810 nm, 940 nm, or 980 nm laser.	

MAR – 6 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

Merit Medical Systems, Inc.
% Ms. Susan Scott
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K090084
Trade/Device Name: *ELAtion*™ Endovenous Laser Procedure Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 27, 2009
Received: March 2, 2009

Dear Ms. Scott:

This letter corrects our substantially equivalent letter of March 6, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090084

Device Name: *ELAtion*™ Endovenous Laser Procedure Kit

Indications for Use:

The *ELAtion*™ Endovenous Laser Procedure Kit is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein and for treatment of incompetence and reflux of superficial veins in the lower extremity. The kit is intended to be used with an 810 nm, 940 nm, or 980 nm laser.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090084